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This Appeals Brief as required by 37CFR 41.37 is in response to the Final Office dated May 5 2008.

Application No.: 10/812,380

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Real Party of Interest:

1. Iftikhar Khan
2. Nazir Khan

Group Art Unit: 3761

Examiner : Leslie Deak

Title: HYBRID ARTERIOVENOUS SHUNT

Attorney Docket: 1800-000001

Mail Stop AF

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

I. Related Appeals and Interferences.

There are no appeals or interferences

II. STATUS OF CLAIMS

These are the claims that are involved in the appeal

1. (amended, appealed) An arteriovenous shunt comprising:

a. an arterial graft comprising a body, a lead end and a terminal end, said lead end

being configured for subcutaneous connection to an artery by anastomosis, wherein said

arterial graft has a first diameter; and

b. a single lumen venous outflow catheter comprising an intake end and depositing end,

said depositing end being configured for insertion through a vein into the right atrium of

the heart, wherein said venous outflow catheter has a second diameter different from said first diameter; and

c. a cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet in blood communication with an outlet:

i. said inlet being disposed about and connected to said terminal end of said arterial graft; and

ii. said outlet being disposed about and connected to said intake end of said venous outflow catheter; wherein said cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter.

2. (previously presented, appealed) The arteriovenous shunt of claim 1 wherein said arterial graft

is made of a biocompatible flexible material.

3. (amended, appealed) The arteriovenous shunt of claim 2, wherein said biocompatible flexible material is polytetrafluoroethylene(PTFE) or other biocompatible material

4. (appealed) The arteriovenous shunt of claim 1, wherein said arterial graft has a diameter from about 2 mm to about 8 mm and a length from about 20 cm to about 60 cm.

5. (appealed) The arteriovenous shunt of claim 4, wherein said arterial graft has a diameter of from about 6 mm to about 8 mm and a length of about 40 cm.

6. (appealed) The arteriovenous shunt of claim 1, wherein said artery is the brachial, axillary, femoral or external iliac artery.

7. (Appealed) The arteriovenous shunt of claim 1, wherein said cuff is polytetrafluoroethylene or polyethylene terephthalate.

8. (Appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 1 mm to about 7 mm and a length of from about 20 cm to about 80 cm.

9. (Appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter from about 5 mm to about 7 mm and a length of from about 40 cm to about 60 cm.

10. (amended, appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter is made of other biocompatible materials.

11. (appealed) The arteriovenous shunt of claim 1, wherein said vein is the cephalic, axillary, jugular, femoral or external iliac vein.

12. (previously presented, appealed) The arteriovenous shunt of claim 1, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

13. (amended, appealed) A system for performing hemodialysis on a patient comprising: a. an arteriovenous shunt comprising:

i. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and

ii. a single lumen venous outflow catheter comprising an intake end and depositing end, said depositing end being configured for insertion through a vein into the right atrium of the heart, wherein said venous outflow catheter has a second diameter different from said first diameter; and

iii. a cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet with blood communication with an outlet:

1. said inlet being disposed about and connected to said terminal end of

said subcutaneous graft; and

2. said outlet being disposed about and connected to said intake end of

said venous outflow catheter; wherein said cuff provides a secure fit for said arterial graft first diameter and said venous outflow catheter second diameter;

14. (previously presented, appealed) The system according to claim 13, wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

15. (original, appealed) The system according to claim 13, wherein said artery is the brachial,

axillary, femoral or external iliac artery.

16. (original, appealed) The system according to claim 13, wherein said vein is the cephalic,

axillary, jugular, femoral or external iliac vein.

17. (amended, appealed) A method of performing hemodialysis on a patient comprising:

a. surgically inserting an arteriovenous shunt into a patient, wherein said arteriovenous shunt comprises:

i. an arterial graft comprising a body, a lead end and a terminal end, said lead end being configured for subcutaneous connection to an artery by anastomosis, wherein said arterial graft has a first diameter; and

ii. a single lumen venous outflow catheter comprising an intake end and depositing end, said depositing end being configured for insertion through a vein into the right atrium of the heart, wherein said venous outflow catheter has a second diameter different from said first diameter; and

iii. a cylindrical cuff operable to direct passage of blood from said arterial graft to said venous outflow catheter, said cuff comprising an inlet in blood

communication with an outlet:

1. said inlet being disposed about and connected to said terminal end of

said arterial graft; and

2. said outlet being disposed about and connected to said intake end of

said venous outflow catheter, wherein said cuff provides a secure fit for said arterial graft first

diameter and said venous outflow catheter second diameter;

b. connecting said arterial graft to a hemodialysis apparatus;

c. collecting blood from the patient through said arterial graft;

d. passing said blood through the hemodialysis apparatus;

e. collecting purified blood from hemodialysis apparatus; and

f. transmitting said purified blood through said cuff into said venous outflow catheter

which is located in the right atrium and the blood is directly deposited into the right

atrium.

18. (previously presented, appealed) The method according to claim 16 wherein said venous outflow catheter has a diameter of about 1 mm smaller than said arterial graft.

19. (original, appealed) The method according to claim 16, wherein said artery is the brachial, axillary, or femoral, external iliac artery.

20. (original, appealed) The method according to claim 16, wherein said the vein is the axillary, jugular, femoral or external iliac vein.

STATUS OF AMENDMENTS

Subsequent to the final rejection and prior to appeal brief, amendments to claims 2, 3, 7, 10, 18, 19 and 20 were made. These were made in compliance with the specifications so that the claims are in proper form.

SUMMARY OF CLAIMED SUBJECT MATTER

An apparatus for positioning a arteriovenous graft and catheter used for subcutaneous access to the vascular system of a patient. The hybrid

arteriovenous shunt is surgically created and comprises a flexible graft and a venous outflow catheter connected to the graft via surgical anastomosis over a cuff. As defined in independent claims 1, 13, 17, the present invention consists of three components: 1. an arterial graft connected to an artery by anastomosis 2. a single lumen venous outflow catheter which is inserted through the vein into the right atrium of the heart and 3. a cuff connecting the arterial graft to the venous outflow catheter. Claim 1 and 13 describe the components of the hemodialysis arteriovenous shunt and claim 17 describes the three components of the arteriovenous shunt and method of operation where the blood is taken from the arterial graft and purified through the machine and is then deposited directly into the right atrium. Refer to page 1 of the specification patent application publication dated September 29, 2005 [0008-0033] and refer to abstract on the cover page and diagrams fig. 1, fig. 2 and fig. 3 of the patent application.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Rejection under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the graded inside diameter of the cuff as set forth in claims 1,13, and 17 must be shown or the feature(s) canceled from the claim. Applicant illustrates and argues that the venous outflow catheter ,12 , is 1mm smaller in diameter than the PTFE graft , 11. However, applicant has not specifically illustrated the graded inside diameter of the cuff to show that it accommodates the varying diameters of the tubes. A "graded" surface indicates a sloping surface, which applicant has not illustrated commensurate in scope with the claims.

2. Claims 1-5,7-10,12-14,17,and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

3. Claims 6,11,15,16,19, and 20 are rejected under 35 U. S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, in further view of US 5,591,226 to Trerotola et al.

4. Claim 10 is rejected under 35 USC 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,591,226 to Trerotola et al.

ARGUMENTS

BACKGROUND

A conventional arteriovenous shunt is a subcutaneous conduit connecting an artery to the vein so that the blood flows continuously through the shunt at arterial pressure into the thin walled veins which are used to a low pressure flow. The graft is used for hemodialysis purpose in end stage renal failure patients. The blood is taken from the conduit dialyzed and injected back into the venous system. Arteriovenous graft patency rate decreases to 60% in the first year to 20

% in three years. The conduit is made of PTFE graft and 80 % of the failure rate is caused by stenos is at the venous end of the graft. (Morbidity and mortality of dialysis. NIH consensus Statement 1993; 11:1-33) The high flow rate from the shunt into the vein at the point of anastomosis to the vein results in vein wall vibration and injury to the vein wall resulting in neo-intimal hyperplasia which causes narrowing of the vein, thrombus formation and graft malfunction. In 1976, LD Baker Jr. teal were the first to use an expanded polytetrafluoroethylene graft in arteriovenous shunt on 72 patients and it is still in use today (see fig 4).

High failure rate prompted inventors to design arteriovenous access to avoid neo intimal hyperplasia. Squitieri believed neo-intimal hyperplasia is caused at the venous anastomosis and patented a device in 2003 where he positioned the venous outflow catheter within the vein to avoid anastomosis. Trerotola in 1977 invented a stunted graft and positioned the venous end of the graft within the lumen of the vein so as to avoid the anastomosis. The fact remains that anastomosis is not the main factor for neo-intimal hyperplasia. It is the vein wall injury from high flow at arterial pressure, which causes vein wall injury and neo-intimal hyperplasia, thrombosis and graft failure. The applicants of the present art positioned the venous outflow catheter in the right atrium to avoid anastomosis and vein wall injury from the high volume blood flow at arterial pressure and dialyzed blood at high pressure.

Rejection of drawing

1.Rejection under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the graded inside diameter of the cuff as set forth in claims 1,13, and 17 must be shown or the feature(s) canceled from the claim. Applicant illustrates and argues that the venous outflow catheter ,12 , is 1mm smaller in diameter than the PTFE graft , 11. However, applicant has not specifically illustrated the graded inside diameter of the cuff to show that it accommodates the varying diameters of the tubes. A "graded" surface indicates a sloping surface, which applicant has not illustrated commensurate in scope with the claim

Response to Rejection of drawing

In regards to this rejection to the drawings under 37 CFR 1.83(a). The cuff of claim 1, 13 and 17 has a flat surface, which is 1 mm in thickness, wraps around the venous outflow catheter at the inlet end and is surgically anastomosed in an end to end

fashion to the arterial graft. Since the cuff does not cover the arterial graft, it does not have a sloped surface.

1) In figure 1, the venous outflow catheter is number 11 and the arterial graft is number 12. However the examiner has reversed these in the rejection, mislabeling the arterial graft as number 11 and venous outflow catheter as number 12. The examiner has misunderstood that the cuff defines a graded inside diameter. It means that the cuff brings together the arterial graft and venous outflow catheter conduits which are varying diameters. The diameter of arterial graft in the present invention is 1mm more in diameter than the venous outflow catheter and the two are brought together by surgical anastomosis of the venous outflow catheter, cuff, and the arterial graft. This is very clear in the specifications. As the cuff has no graded surface it is submitted that this rejection of claim 1,13 and 17 be withdrawn.

Rejection

Rejection Of claims 1-5, 7-10, 12-14, 17 and 18 under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

Response to Rejection

The examiner states that Squitieri's device is substantially similar to the claimed invention of the applicant. In claim 1, Squiteiri discloses an arteriovenous shunt system comprising an arterial graft (53) with a lead end (62) anastomosed to an artery and terminal end connected to needle access site (80), which acts as a connecter that corresponds to applicant's cuff. The system further comprises a venous outflow catheter (65) with an outflow end that is capable of being inserted through a vein (40) into the right atrium of the heart (see figs 6-9) and an inflow end that is connected to connector (80) (see column 4). The access site 80, corresponding to applicant's cuff, directs passage of blood from the arterial catheter to the venous catheter, and is in communication with

the terminal end of the arterial graft and the inlet end of the venous catheter (see figs 6-9,colum 5,lines 19-60).

The claimed invention is different from Squiteiri in the following ways:

1. Squiteiri recognized that the neo-intimal hyperplasia at the anastomotic site accounts for 60 – 80 % shunt failure - see column 6, line 80. He positioned the venous outflow catheter into a large vein to avoid anastomosis of the graft with the vein (Column 6, line 65, Column 3, fig 7 and 8) Claim 16, 8 and 1 – The venous outflow catheter of Squiteiri (65) remains in the **unnamed vein** whereas in our claimed invention, (claim 1,13,17) the venous outflow catheter remains within the right side of the heart, called right atrium. Squitieri's invention was patented because of the position of the venous outflow catheter within the unnamed vein and therefore the length of the catheter in Squitieri's invention is shorter than the claimed invention. Claims 16,8 and 1 in Squitieri's patent puts a limitation on Squitieri's invention with regard to the length of the catheter and his claims make the length of the catheter in Squitieri's invention shorter than our invention because our catheter has to go to the heart. Because of the claim limitation length of the venous outflow catheter in Squitieri's invention, his catheter cannot be advanced beyond the **unnamed vein** to any other position. Therefore